**SECTION 5: 510(k) SUMMARY**

MAR 2 9 2012

**A. Submitter Information**

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|---|---|
| Submitter's Name: | Ostial Corporation |
| Address: | 510 Clyde Avenue<br>Mountain View, CA 94043 |
| Telephone: | 650-903-9100 |
| Fax: | 650-903-9119 |
| Email: | kvonhoffmann@ostialcorp.com |
| Contact Person: | Kaitlin von Hoffmann |
| Date of Preparation: | March 9, 2012 |

**B. Subject Device**

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|---|---|
| Trade Name: | Flash PTA Balloon Dilatation Catheter |
| Common/Usual Name: | Balloon Catheter |
| Classification Name: | Catheters, Angioplasty, Peripheral, Transluminal |
| Product Code: | LIT per 21 C.F.R. 870.1250 |

**C. Device Description:**

The Flash PTA Balloon Dilatation Catheter is indicated for use in Percutaneous Transluminal Angioplasty in the peripheral vasculature at aorto-ostial locations, including iliac, renal and carotid arteries. This catheter is not intended for use in coronary arteries. The Flash PTA Balloon Dilatation Catheter is a 0.014" guidewire-compatible, rapid exchange (RX) angioplasty balloon catheter with proximal anchoring. The device uses a dual balloon design featuring a compliant anchoring balloon, which enables the operator to precisely position the catheter at aorto-ostial anatomies and prevent distal migration of the balloon during angioplasty. The second semi-compliant high pressure balloon allows for luminal dilatation.

**D. Intended Use:**

The Flash PTA Balloon Dilatation Catheter is indicated for use in Percutaneous Transluminal Angioplasty in the peripheral vasculature at aorto-ostial locations, including iliac, renal and carotid arteries. This catheter is not intended for use in coronary arteries.

**E. Summary of Similarities and Differences in Technological Characteristics, Performance and Intended Use:**

The Flash PTA Balloon Dilatation Catheter that is the subject of this 510(k) is an extension of a product line of the same name, which was cleared via 510(k) #K102482 on February 25, 2011. Minor design and process changes to decrease the crossing profile of the device have been implemented. This submission includes devices with balloon diameters ranging from 4.0 to 6.0mm and balloon lengths of 14 to 19mm. The new sizes are 135cm in length and compatible with 6 French guide catheters.

**F. Performance Data:**

Bench testing performed on the Flash PTA device included the following:

- Balloon crossing profile
- Catheter shaft diameter
- Angioplasty balloon rated burst pressure and maximum burst pressure
- Anchoring balloon rated burst volume
- Balloon compliance and diameter
- Balloon inflation and deflation time
- Angioplasty balloon fatigue

- Anchoring balloon fatigue
- Catheter bond and tip pull strength
- Catheter torque strength, flexibility and kink
- Simulated use
- Radiopacity

All test results demonstrate that the materials, manufacturing process, and design of the Flash PTA Balloon Dilatation Catheter meet the established specifications necessary for consistent performance according to its intended use.

**G. Conclusions:**

The Flash PTA Balloon Dilatation Catheter is indicated for use in Percutaneous Transluminal Angioplasty in the peripheral vasculature at aorto-ostial locations, including iliac, renal and carotid arteries. This catheter is not intended for use in coronary arteries. The purpose of this 510(k) is to request clearance for an extension of the Flash PTA Balloon Dilatation Catheter product line, which was initially cleared via 510(k) #K102482 on February 25, 2011. All test results demonstrate that the Flash PTA Balloon Dilatation Catheter meets all predetermined design verification and validation acceptance criteria.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR 2 9 2012

Ostial Corporation
c/o Ms. Kaitlin von Hoffman
510 Clyde Ave.
Mountain View, CA 94043

Re: K120738
Trade/Device Name: Flash PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II (two)
Product Code: LIT, DQY
Dated: March 9, 2012
Received: March 12, 2012

Dear Ms. Von Hoffmann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

M. D. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**SECTION 4: INDICATIONS FOR USE STATEMENT**

510(k) Number: K120738

Device Name: Flash PTA Balloon Dilatation Catheter

Indication For Use: The Flash PTA Balloon Dilatation Catheter is indicated for use in Percutaneous Transluminal Angioplasty in the peripheral vasculature at aorto-ostial locations, including iliac, renal and carotid arteries. This catheter is not intended for use in coronary arteries.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K120738